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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3761

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/656,973

Applicant(s)

ROSENBERG, MEIR

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/12/04, 3/30/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 9 and 17-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a system and method for controlling cerebrospinal fluid flow through a shunt that uses an internally placed sensor to control the fluid flow, does not reasonably provide enablement for a sensor that measures the volume of the ventricular cavity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The Examiner must weigh several factual considerations in order to determine whether applicant's disclosure is enabling or requires "undue experimentation" to make and use the claimed invention. (*In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.) These factual considerations include the scope of the claims, the nature of the invention and scope of the prior art, level of one of ordinary skill in the art, the existence of working examples of the claimed invention, and quantity of experimentation required to make and use the invention based on the content of the disclosure. See MPEP 2164.01.

With regard to the scope of the claims, Applicant claims the use of a volume sensor to control the operation of the adjustable resistance shunt, but provides no

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guidance on how such a volume determination is to be made. A person of ordinary skill in the art would not be able to make or use the invention with the information in the disclosure without undue experimentation to determine how to measure the volume of brain ventricle. See MPEP 2164.01.

The prior art discloses means of calculating ventricular volume via pressure measurements as well as volumetric CSF removal via measurement of CSF volume that flows through the shunt. The prior art fails to disclose an implantable means to measure the volume of a body cavity such as a brain ventricle. In fact, such sensors are only now being developed, according to the research flyer from the University of Illinois at Chicago (http://vienna.chc.uic.edu/jobs/Flyer/Volume_sensor.pdf). Examiner has found one method and device for measuring ventricular volume via a noninvasive impedance measurement (US 4,819,648 to Ko). However, the impedance measuring apparatus requires an exciting coil and a detector coil placed outside the patient's cranium, none of which is disclosed or illustrated by Applicant.

Since the prior art contains no indications of how to effect a volumetric measurement of a patient's brain ventricles, a person of ordinary skill in the art would not be able to make and use the invention. Applicant fails to disclose the means by which such a measurement is made in the instant invention, and the prior art fails to show that such a measurement is familiar to one of ordinary skill in the art. Thus, one of ordinary skill in the art would be unable to practice the invention as claimed based on Applicant's disclosure.

The prior art and the disclosure both fail to show any working examples of the invention as claimed. The specification is not required to actually show an example of a working model. However, a "working example" may be based on work already performed, including a prediction of expected results. Applicant has not disclosed any such work to develop a volumetric sensor. Lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02. Since the volumetric sensor as claimed has not yet been developed, (see University of Chicago flyer), Applicant's lack of a working example in the disclosure indicates that a person of ordinary skill in the art would be unable to make or use the invention.

If little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. See, e.g., *Chiron Corp. v. Genentech Inc.*, 70 USPQ2d 1321. Examiner has found that little is known in the prior art about devices and methods for measuring ventricular volume. Since applicant has failed to disclose and details with regard to the construction and mode of operation of a ventricular volume sensor, a person of ordinary skill in the art would be required to undertake large amounts of experimentation in order to develop a sensor for measuring the volume of a brain ventricle.

The finding of a lack of enablement is a determination of law based on the underlying facts. See *In re Vaeck*, 20 USPQ2d 1438; *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 224 USPQ 409. According to *In re Bowen*, (181 USPQ 48), the

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minimal requirement is for the examiner to give reasons for the uncertainty of the enablement. In the instant case, Examiner has found that brain ventricle volume sensors have yet to be developed. Thus, the instant application lacks enablement since applicant has failed to describe the construction and operation of his ventricular volume sensor.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-8, 13-16 rejected under 35 U.S.C. 102(e) as being anticipated by US2003/0004495 A1 to Saul.

Saul discloses the invention as claimed in the specification and figures.

Specifically, Saul discloses a method and device for volumetric removal of CSF from a hydrocephalus patient with an implantable, controllable shunt system. Saul discloses a ventricular catheter 12 and peritoneal catheter 14 that are connected via a flow control valve 30. The catheters operate to shunt CSF from the brain ventricle to the peritoneal cavity (see paragraph 0043). The system is operated via controller 32 that operates the movement of the valve 30 with power from source 34.

When CSF fluid drainage is being controlled by volume, sensing device 36 sends signals to the controller 30, which adjusts the valve between an open and closed position based on the signals sent to the controller from the sensor (see paragraphs 0044 and 0045). The sensor reports the volume of flow through the valve, and once the desired volume has been reached (which the controller must determine by comparing the measured value to a desired value), the controller sends an electrical control signal to the valve, adjusting the resistance of the valve to open (decreased resistance) or closed (increased resistance) in order to continue or halt fluid flow (see paragraphs 0045, 0046).

With regard to claims 5, 8, and 16, the procedure disclosed by Saul may be repeated, if desired, a set number of times per day, with the time between treatments set to allow the CSF to drain from a reservoir, allowing the patient to adjust to the current resistance of the valve, until a total desired volume of CSF is removed from the ventricular space (see paragraph 27).

With regard to claims 13-15, Saul specifically discloses that his apparatus and method are particularly intended for patients who experience hydrocephalus with "normal" intracranial pressures, i.e, normal pressure hydrocephalus (see paragraph 15).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0004495 to Saul as applied to claim 1 above in view of US 2003/0032915 A1 to Saul.

Saul 495 discloses the apparatus and method as claimed with the exception of adding a second sensor to the shunt device. Pressure sensors are well known in the art of hydrocephalus control shunts, as taught by Saul 915. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a second sensor and sensing operation to the device and method disclosed by applicant since it has been held that duplication of the working parts of a device or steps of a method involves only routine skill in the art. See MPEP 2144.04.

7. Claims 9 and 17-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0032915 A1 to Saul.

Applicant claims a device and method for controlling CSF shunting based on a volumetric measurement. While the disclosure does not enable the use of a volume sensor, the disclosure does enable a device and method for controlling CSF shunting with a sensor that may calculate volume changes based on a pressure differential, as is known in the art.

Saul 915 discloses an apparatus and method for controlling CSF drainage through a shunt that uses a pressure differential to determine when there is an increased volume of CSF in the ventricles. Using a change in pressure, rather than a single pressure measurement, enables one to monitor the volume of CSF in the

ventricles even when the patient's standalone intracranial pressure remains within a normal range. By subtracting a current pressure value from a baseline pressure value, Saul determines a change in pressure that is indicative of increased volume of CSF in the measured space (see paragraph 0031).

The device includes a ventricular catheter 12, peritoneal catheter 14, and a flow control element 16/30 disposed between the two catheters (see FIG 3). The flow control element 30 is controlled by controller 32, which is programmed to operate the valve in response to changes in the measured pressure differential (see paragraph 0033).

Pressure sensor 40 is located on the ventricular catheter 12, with an electrical output 42 that is fed to controller 44. With regard to claims 21-23, the controller drives flow control element 48 based on a variety of programmed algorithms that control drainage of CSF.

With regard to claims 24-26, Saul fails to disclose a second sensor in the system. However, it would have been obvious to one having ordinary skill in the art at the time of invention to add a second sensor and sensing operation to the device and method disclosed by applicant since it has been held that duplication of the working parts of a device or steps of a method involves only routine skill in the art. See MPEP 2144.04.

With regard to claim 26, Saul fails to disclose that the valve is configured for implantation in the peritoneal cavity of the patient. Absent any showing of new or unexpected results of such a change in the location of the valve, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the valve in the peritoneal cavity, since it has been held that rearranging parts of an invention involves only routine skill in the art. See MPEP 2144.04.

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8. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0032915 A1 to Saul as applied to claim 17 above in view of US 2003/0004495 to Saul.

Saul 915 discloses the device as claimed with the exception of a timed shut-off mechanism. Saul 495 discloses that his device may be controlled by a timer or programmable controller in order to control the valve based on a predetermined time schedule in order to prevent overdrainage of CSF from the patient during a single time period (see paragraph 0027). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add an automatic shutoff to the CSF shunt system in order to prevent overdrainage of CSF from a patient during a particular time period.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

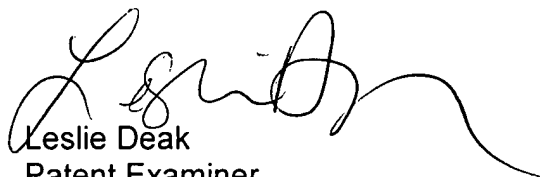
- a. US 4,819,648 Ko
 - i. Impedance measurement that extrapolates ventricular volume
- b. US 2004/0068221 Silverberg et al
 - ii. Treatment for normal pressure hydrocephalus

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Leslie Deak', with a long, sweeping horizontal line extending to the right.

Leslie Deak
Patent Examiner
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13 October 2005